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October 29, 2024

**VIA ECF**

The Honorable Renée Marie Bumb  
United States District Court Judge  
District of New Jersey  
Mitchell H. Cohen Building & U.S. Courthouse  
4th & Cooper Streets, Room 1050  
Camden, NJ 08101

**Re: *In re: Valsartan, Losartan, and Irbesartan Products Liability  
Litigation.*, U.S. District Court for the District of New Jersey; Case  
No. 1:19-md-02875**

Dear Judge Bumb:

Teva Pharmaceuticals USA, Inc. (“Teva”) submits this letter in follow-up to the October 10, 2024 Case Management Conference, at which the Court found that there were important outstanding issues to be resolved prior to conducting the TPP economic loss trial and that the Parties should pivot back to preparation of the bellwether trials. ECF 2899.<sup>1</sup> Three of the main issues identified by the Court are: (1) the need to reconcile MTD Opinion 2 [ECF [728](#)] and the Opinion on TPP Trial Summary Judgment Motions [ECF [2694](#)] with respect to the questions of standing, worthlessness, and the benefit-of-the-bargain measure of damages; (2) determining the implications of the Court’s ruling excluding Professor Conti’s opinion on retroactive worthlessness with respect to the continuing viability of Plaintiffs’ express warranty claim and other claims resting on the same measure of damages going forward; and (3) the role of general causation evidence in this MDL, whether as part of the bellwether workup or at trial of any economic loss claims. *See, e.g.*, Oct. 10, 2024 Tr. [ECF [2906](#)] at 47:16-52:1, 72:14-73:23, 74:4-7, 78:3-25.

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<sup>1</sup> Teva is not a defendant in the first six bellwether trials randomly selected for work-up by Special Master Vanaskie in his Case Management Order entered October 22, 2024 [ECF [2912](#)], but nevertheless has a significant interest in the overall progression of these proceedings, including all matters relating to general causation, and therefore respectfully submits this letter to present its views to the Court. Teva anticipates that other defendants not part of the initial bellwether trial cases would support the requests in this letter.

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Teva stands ready to proceed however the Court deems most appropriate but proposes the following framework, similar to the one used by Judge Rosenberg in the Zantac MDL, to provide an efficient resolution of the myriad open issues in this long-standing MDL.

First, Teva respectfully requests leave to submit renewed summary judgment briefing on Plaintiffs' express warranty claims and other claims resting on the same measure of damages. The Court's decision finding that Professor Conti's proposed testimony is unreliable and fails to fit the facts here is fatal to Plaintiffs' express warranty claims (as well as other claims resting on the same measure of damages) and a ruling to that effect would narrow the economic damages claims and issues in the litigation. Conversely, Plaintiffs' new attempt to backtrack on their strategic decision years ago to go all-in on their "worthlessness" theory, "re-open the expert record," and pivot to a "conjoint or similar analysis" [ECF [2911](#) at 12-14], ignores Judge Kugler's dismissal and class certification rulings and would set this MDL back years. A renewed summary judgment motion in light of the Court's Rule 702 rulings is both the more efficient path and the next logical step in the progression of the TPP economic loss track. Of course, this should all occur while the parties proceed with preparation of the bellwether trials in the personal injury track.

Second, as an initial step to facilitate the overall personal injury bellwether track, as well as a step to address the Court's question regarding the role of general causation evidence in the economic loss tracks, Teva proposes updated Rule 702 hearings for the general causation experts that comport with Rule 702's recently reaffirmed requirements. Amended Rule 702, which was amended after the initial general causation rulings, has confirmed the Court's gate-keeping function requires more than the "very, very limited" hearings Judge Kugler undertook two and a half years ago. March 2, 2022 Tr. [ECF [1959](#)] at 93:1-93:2. A more detailed examination of the evidence around general causation is also consistent with the more fulsome review undertaken by Judge Rosenberg in the Zantac MDL. If it would be helpful to the Court, Teva would also be happy to arrange a "science day" to provide a lens into the current scientific and medical evidence at the heart of this litigation, including new developments since Judge Kugler's limited Rule 702 hearings.

Teva submits these proposals for the Court's consideration and welcomes the Court's direction as to what submissions or hearings would best assist the Court.

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**A. Request for Leave to File Partial Summary Judgment Motion**

With respect to the first proposal, the Court asked at the October 10 Case Management Conference whether, in light of the exclusion of Professor Conti's retroactive worthlessness opinion, "aren't we in summary judgment land? Because if it's just strictly argument, shouldn't have been sold, zero value, that's strictly argument." Oct. 10, 2024 Tr. [ECF [2906](#)] at 28:18-29:22. The Court noted and defense counsel also argued that the exclusion of Professor Conti's worthlessness opinion was a changed circumstance since entry of Judge Kugler's summary judgment ruling, potentially supporting renewed summary judgment. *Id.* at 30:20-31:12, 32:9-36:2, 71:7-74:7.

Teva believes a renewed summary judgment motion would help dispose of or narrow the issues for trial as contemplated by Rule 56, and respectfully requests leave of the Court pursuant to Rule 56 and Case Management Order No. 23 to file a renewed summary judgment motion on the limited grounds described in this letter. This Court has broad discretion to consider a renewed summary judgment motion, and the initial denial of a summary judgment motion does "not create any bar to the court's later reconsideration of [a] renewed motion." *Krueger Assocs. v. Am. Dist. Tel. Co.*, 247 F.3d 61, 65 (3d Cir. 2001). Here, the exclusion of Professor Conti's retroactive worthlessness opinion is a significant changed circumstance with implications for the viability of Plaintiffs' express warranty claims and other claims (including certain states' consumer protection statutory claims)<sup>2</sup> that rely on the same or similar measures of damages. As the Court observed at the October 10 hearing, Plaintiffs made a "strategic choice to go ... all in with the worthless, one word, theory." Oct. 10, 2024 Tr. [ECF [2906](#)] at 73:20-23. Because Plaintiffs lack admissible evidence to proceed on that theory, it is ripe for a renewed summary judgment motion.

Plaintiffs' recent submission and argument to Special Master Vanaskie, by contrast, seeks to backtrack on Plaintiffs' strategic decision at the outset of this MDL to go all-in on their "worthlessness" theory of damages. Plaintiffs now seek to reverse course back to the earliest stages of this case and to advance a diminution of value (or "worth less") theory they abandoned years ago. That would set this MDL back years. Specifically, Plaintiffs now propose to use "a conjoint or similar

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<sup>2</sup> Many of Plaintiffs' claims are subject to the same or similar measures of damages as the benefit-of-the-bargain measure applicable to Plaintiffs' breach of express warranty claims. Teva anticipates addressing all applicable claims in a renewed summary judgment motion, but has focused here on the breach of express warranty claims, which were the primary focus of discussion at the October 10 Case Management Conference.

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analysis” using “a market research assessment” to measure the value consumers of the at-issue valsartan products place on the attributes of that product, taking into account both the presence of nitrosamines in the product as well as its therapeutic value.” ECF [2911](#) at 12. Plaintiffs also propose a new expert report to “provide calculations and analysis of available sales data (quantity and pricing) as to the at-issue valsartan sold by the trial defendants.” *Id.* at 13. And Plaintiffs propose to “re-open the expert record for the bellwether TPP subclass trial” to address the Court’s exclusion of Professor Conti’s “worthlessness” opinion, on the rationale that Plaintiffs relied on “the law of the case that their claims, damages theory, and Dr. Conti’s economic model and opinions all were to be put before a jury.” *Id.* at 14.

The only pending proposal contrary to the law of the case is Plaintiffs’ attempt to fall back on a “worth less” (two words) theory. Judge Kugler’s MTD Opinion 2 rejected that theory as speculative at the pleading stage because Plaintiffs’ complaint “fails to allege facts which would permit a factfinder to value the purported injury” other than by having “the factfinder resort to mere conjecture to value their purported injury,” which “is insufficient to confer standing.” ECF [728](#) at 11, 13. Nothing has changed since MTD Opinion 2 that would enable Plaintiffs to proceed on a “worth less” theory at this late stage. Indeed, the bar is even higher at this stage, where evidence is required to establish standing or support damages, but Plaintiffs still have no “facts which would permit a factfinder to value the purported injury” without having “the factfinder resort to mere conjecture.” The conjecture problem that doomed Plaintiffs’ “worth less” theory of standing at the pleading stage equally dooms a “worth less” theory of standing or damages today.

Moreover, Judge Kugler’s class certification order confirmed that the consumer and TPP classes satisfied Rule 23’s predominance requirement specifically on the question of whether Defendants’ VCDs were “**worthless** on the date of sale.” ECF [2261](#) at 20, 22-23, 36-38 & n.27 (emphasis added). Judge Kugler never found predominance satisfied under Rule 23 with respect to a “worth less” theory, nor could he have done so as Plaintiffs have never offered any expert or methodology capable of measuring diminution-of-value damages for a “worth less” theory of damages on a class-wide basis. Nor did Plaintiffs offer a “conjoint or similar analysis” as their proposed class-wide method of measuring damages under their “worthlessness” theory at the class certification stage or any previous stage in this MDL. Revisiting Plaintiffs’ theory of damages at this late date, or their economic model and methodology of measuring class-wide damages, would require de-certifying every class and subclass certified by Judge Kugler on Plaintiffs’

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“worthlessness” theory of damages and starting all over on a diminution-of-value theory and/or a new economic model and methodology of measuring damages.

Plaintiffs’ rationale that they have relied on “the law of the case” and assumed Professor Conti’s opinions were to be “put before a jury” does not hold water. Plaintiffs have always known Professor Conti’s retroactive worthlessness opinion would have to survive a Rule 702 challenge at the trial stage, and it did not. Judge Kugler was clear in his class certification order that he was accepting Professor Conti’s opinions “[a]t [the] class certification stage,” when “the methodology of an expert need not be perfect or even legally correct.” ECF [2261](#) at 89. He did not decide the admissibility of Professor Conti’s opinions or model at trial. Likewise, Judge Kugler’s summary judgment ruling did not address the pending Rule 702 motions as to the Parties’ respective damages experts or motions in limine, leaving these trial issues for his successor to address. *See* March 27, 2024 Tr. [ECF [2698](#)] at 4-5. He simply declined at the summary judgment stage, prior to the issuance of Rule 702 rulings on the parties’ damages experts, to find the absence of a genuine dispute of material fact on damages. *See* ECF [2694](#) at 56-70. Thus, there is not and never has been “law of the case” that Professor Conti’s economic model and opinions were to be put before a jury. Plaintiffs made a strategic decision years ago to proceed solely on a retroactive worthlessness theory of damages based exclusively on Professor Conti’s economic model and opinions, which carried with it the burden to satisfy Rule 702’s admissibility requirements to admit their expert’s opinions on that theory at trial. The fact that Plaintiffs could not satisfy their burden is not a justification to set this MDL back by years.

Plaintiffs’ benefit-of-the-bargain claims and similar claims at trial must stand or fall on the viability of their theory of retroactive worthlessness, and whether there is sufficient evidence to present a genuine dispute of material fact to the jury on that theory. Teva believes briefing a renewed summary judgment motion on this discrete subset of issues would facilitate the ultimate disposition of this case, or alternatively would enable the Court to substantially narrow the issues for trial. A renewed summary judgment motion does not impact the parties’ preparation of the bellwether personal injury cases for trial as directed by the Court and the two processes can proceed on simultaneous tracks.

## **B. Request for 702 Hearings on General Causation Experts**

Teva’s second proposal pertains to the subject of general causation, and is directly relevant to the bellwether workup, as reflected in the Parties’ recent

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submissions to Special Master Vanaskie. *See* ECF [2910](#) at 11-14 (Defendants' submission regarding general causation issues for bellwether track); ECF [2911](#) at 7-9 (Plaintiffs' submission regarding general causation issues for bellwether track). General causation is also relevant to the economic loss tracks, as the Court has expressed concerns that, with Plaintiffs seeking to present evidence "like the jury's going to hear that it had a genotoxic contaminant; that it was unsafe; that the plaintiff has to show that matters, that all says to me that the defendants have been quarreling about, which is how can they try this case without causation. \* \* \* I just don't see how the case can be tried without causation, I don't; I just simply don't." Oct. 10, 2024 Tr. [ECF [2906](#)] at 48:1-19. Thus the core scientific issues of general causation are central to all aspects of this MDL proceeding, including both the personal injury bellwether cases designated by Special Master Vanaskie in his October 22 Case Management Order and any economic loss trial.

Teva renews its request for full Rule 702 hearings on the Parties' general causation experts in light of amended Rule 702 and the evolving scientific literature. Although Judge Kugler issued Rule 702 rulings with respect to the parties' general causation experts, he did so at an early stage of the case, prior to: the work-up of specific bellwethers; Special Master Vanaskie's designation of the first track of six personal injury bellwethers to proceed to trial; publication of certain studies evaluating patient populations that took at-issue VCDs; and the amendment of Rule 702. Judge Kugler's Rule 702 hearings also took place under narrow parameters, with the Court holding abbreviated hearings on only three experts selected by the proponents of the expert testimony to testify live, with cross-examination only of the selected experts, and with cross-examination limited to opinions submitted by the experts in sworn certifications. *See* ECF [1958](#) at 1-2; ECF [1974](#) at 1.

At that time, rather than applying the heightened level of judicial scrutiny required by the subsequent amendments to Rule 702, the Court found the mere presence of an explanation and a methodology to be sufficient based on what it perceived to be its "very, very limited role" under Rule 702. March 2, 2022 Tr. [ECF [1959](#)] at 93:1-93:2. Further, the Court determined that any criticisms or gaps such as how an expert *applied* his or her methodology to the underlying data and whether such data itself is reliable were to be addressed through cross-examination and, ultimately, would be left to the jury to sort out at trial. *See, e.g., id.* at 142:12-16, 151:4-7, 153:1-3, 154:23-155:5, 155:9-12, 158:8-10. Teva submits that amended Rule 702 requires further analysis and strict application of the Court's gate-keeping function prior to any case reaching the jury.



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Moreover, significant issues remain as to the Court's prior Rule 702 rulings which require this Court's consideration and clarification. On March 18, 2022, Defendants filed a Joint Motion for Clarification Regarding *Daubert* Hearing Order 1, which seeks confirmation that all causation evidence as to NDEA and any cancer type other than pancreatic is precluded. *See* ECF [1976](#). Adjudication of the Motion for Clarification was deferred while the focus of the MDL proceeding shifted to the class cases. Accordingly, Plaintiffs never filed a formal opposition, and the Motion for Clarification has been held in abeyance for the past two and a half years. Plaintiffs have indicated, and Teva agrees, that this is a threshold issue that is ripe for decision as the Parties move toward preparation of the bellwether personal injury cases for trial. And Special Master Vanaskie confirmed at the October 22 Case Management Conference that the Motion for Clarification is a matter to be submitted to the Court for its determination.

Teva therefore respectfully submits that more fulsome Rule 702 hearings are warranted to address the general causation testimony to be heard at trial—both as to any remaining claims in the TPP Trial and in the forthcoming personal injury bellwethers under the amended Rule 702 and in light of the evolving literature. Again, this process could move forward contemporaneously with the remaining work-up of the first track of six bellwether personal injury cases for trial and should result in no delay.

To the extent it would be helpful to the Court, Teva would also be happy to arrange a “science day” to address the scientific and medical evidence in this case. Counsel for both Plaintiffs and Defendants previewed some of the evidence and issues pertaining to general causation at the recent CMC, but as indicated in the Parties' July 9, 2024 Joint Status Report (ECF [2770](#)), Teva believes the Court may find a substantive presentation addressing the state of the science regarding NDMA and NDEA and cancer causation helpful. *See id.* at 39:13-40:4, 60:21-63:6. The general causation issues include questions as to whether there is reliable scientific evidence that VCDs containing NDMA or NDEA cause or increase the risk of cancer, and if so, what cancers and at what threshold dose. *See In re Zantac (Ranitidine) Prod. Liab. Litig.*, 644 F. Supp. 3d 1075, 1109 (S.D. Fla. 2022) (“The Court concludes that the Plaintiffs must identify a threshold dose range at which ranitidine can cause cancer . . . Courts universally reject general causation theories based upon the idea that any amount of a carcinogen, no matter how small, is actionable because an infinitesimal risk can neither be proven nor disproven.”).

Thus, if the Court believes it would be helpful, Teva stands ready to facilitate

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the conduct of an in-person “science day,” during which the Court could hear from experts on both sides regarding the core scientific issues that are central to this MDL proceeding. An orderly presentation of the scientific issues to the Court could be scheduled at the Court’s convenience without in any way delaying the work-up of the bellwether personal injury cases for trial.

Again, Teva respectfully submits these proposals with the goal of facilitating the Court’s resolution of issues identified by the Court at the October 10 hearing and clarifying the issues for trial. Teva stands ready to proceed in whatever manner would be most helpful to the Court.

Sincerely,

/s/ Gregory E. Ostfeld  
Gregory E. Ostfeld

cc: All counsel of record (via ECF)